

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The comparison between the effectiveness of using virtual reality games and conventional intervention on social-communication skills of school-aged children with autism spectrum disorder

Protocol summary

Study aim

Comparing the effectiveness of joint attention interventions by virtual reality games and conventional treatment on the improvement of social-communication skills of children with autism

Design

Two arm, parallel group, double blind, randomized, sham controlled clinical trial of 32 participants. Randomization was computerized with concealed randomization sequence carried out by www.sealedenvelope.com.

Settings and conduct

Eligible participants will be recruited selected from autism schools in Tehran City, Iran, using a convenience sampling method. The participants will randomly assign to the target and control groups. The study is double-blind and participants and assessors will be blinded to randomized group allocation. Both groups will receive the intervention in the speech and language therapy rooms of the schools. VR Sessions will occur 3 days per week, with at least 48 h between sessions. A total of 15 VR sessions are completed over a 5-week period. A follow-up appointment at the assessment site will be approximately one month after the end of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: A clinical diagnosis of autism spectrum disorder (ASD) Exclusion criteria: Inability to understand and follow simple instructions; History of seizures, epilepsy, migraines, vertigo, psychosis, or photophobia

Intervention groups

Children in the intervention group will receive joint attention interventions through virtual reality (VR) games with VR glasses, while children in the control group will use VR glasses only to watch a simple animation. Furthermore, both groups receive conventional speech and language therapy during the experiment.

Main outcome variables

social communication; initiating joint attention;

responding to joint attention; Visual pursuit; Eye contact

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221224056907N1**

Registration date: **2023-01-31, 1401/11/11**

Registration timing: **prospective**

Last update: **2023-01-31, 1401/11/11**

Update count: **0**

Registration date

2023-01-31, 1401/11/11

Registrant information

Name

Talieh Zarifian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-24, 1401/12/05

Expected recruitment end date

2023-04-04, 1402/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between the effectiveness of using virtual reality games and conventional intervention on social-communication skills of school-aged children with autism spectrum disorder

Public title

Effect of virtual reality games in autism spectrum disorder (ASD)

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Monolingual in Persian Parents consent for inclusion in the experiment A clinical diagnosis of autism spectrum disorder (ASD)

Exclusion criteria:

History of problems with virtual reality games History of seizures, epilepsy, migraines, vertigo, psychosis, or photophobia Obvious vision or hearing problem Severe stereotyped behaviors and hyperactivity Severe sensory or balance impairments Inability to understand and follow simple instructions Lack of proper psychomotor development

Age

From **7 years** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

The blocked randomization method is used to allocate participants to two groups. This allocation is done in several steps. First, using the online software application provided by sealedenvelope.com, a random sequence is generated with blocks of four. Then, to hide the random allocation, sequentially numbered, opaque sealed envelopes (SNOSE) are used in a random sequence.

Based on the sample size, 32 envelopes with aluminum foil inside (to prevent "hot lighting") are prepared. Each entity in the random sequence is noted on a card and is replaced in the envelope in numbered envelope. Finally, the envelopes are sealed and placed in boxes, respectively. At the time of registration of participants, according to the order of entry of eligible participants into the study, one of the envelopes is opened respectively and so the participant's assigned group is revealed. In this approach, the experts who check the inclusion and exclusion criteria and the experts who do the allocation process are independent.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double-blind and participants and assessors will be blinded to randomized group allocation. Children in the intervention group will receive joint attention tasks through virtual reality (VR) games with VR glasses, while children in the control group will use VR glasses only to watch a simple animation. Furthermore, both groups receive the conventional speech and language therapy during the experiment. The assessors are also not aware of which intervention participants have received and whether the assessments are pre- or post intervention.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of University of Social Welfare and Rehabilitation Sciences

Street address

Kodakyar Ave., Daneshjo Blvd., Evin, Tehran

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Province

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Postal code

1985713871

Approval date

2022-12-21, 1401/09/30

Ethics committee reference number

IR.USWR.REC.1401.177

Health conditions studied**1****Description of health condition studied**

Autism spectrum disorder

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes**1****Description**

Joint attention skills

Timepoint

Assessment of joint attention skills at the beginning of

the study (baseline, before the start of the intervention), at the end of the study and one month after the end of the study (follow-up)

Method of measurement

Floreo questionnaire; pre- and post-assessment game

Secondary outcomes

1

Description

Social-communication skills

Timepoint

Assessment of joint attention skills at the beginning of the study (baseline, before the start of the intervention), at the end of the study and one month after the end of the study (follow-up)

Method of measurement

Autism Classification System of Functioning: Social Communication (ACSF: SC)

Intervention groups

1

Description

Intervention group: Virtual reality games in order to make improvement joint attention through VR glasses, 15 sessions with an interval of 48 hours, three sessions per week, each session includes one or two virtual reality games, and the duration of each game is about five minutes. There is a three to five minute break between each game.

Category

Rehabilitation

2

Description

Control group: A simple animation through VR glasses, 15 sessions with an interval of 48 hours, three sessions per week, each session includes one or two animations with virtual reality characters, and the duration of each animation is about five minutes. There is a three to five minute break between each animation.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Aein Mehrvarzi School

Full name of responsible person

Mehdi Ghandazade

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

University of social welfare and rehabilitation sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tose'e Darman Sarv

Full name of responsible person

Hassan Yazdanian

Position

Research and development lead

Latest degree

Ph.D.

Other areas of specialty/work

Medical Engineering

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

Contact**Name of organization / entity**

Tose'e Darman Sarv

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The results of this study will be published in peer-reviewed journals.

When the data will become available and for how long

After publishing results

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Data will be available only for research purpose.

From where data/document is obtainable

Through sending an email to:
hassanyazdanian@gmail.com

What processes are involved for a request to access data/document

The requested data will be sent as soon as possible after receiving the email.

Comments